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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,658	01/26/2004	Michael J. Munchhof	PC23317A	1215

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

COPPINS, JANET L

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/765,658

Applicant(s)

MUNCHHOF, MICHAEL J.

Examiner

Janet L. Coppins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

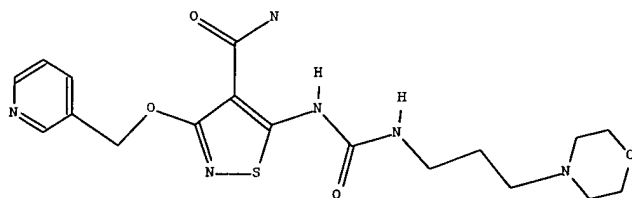
Claims 1-15 pending in the instant application.

Information Disclosure Statement

1. Applicant's Informational Disclosure Statement, filed February 24, 2004, has been considered by the Examiner. Please refer to the Applicant's copy of the PTO-1449 form submitted herewith.

Election/Restrictions

2. Applicants' election **with** traverse of Group I, claims 1-13, drawn to compounds and their compositions according to formula (I), in the response filed October 8, 2004, is acknowledged. A further election of the compound of Example 15, found on page 31 of the specification:



is also acknowledged.

Regarding the Applicants' arguments that Restriction of the Markush group of the instant claims is improper, the Examiner would also like to direct Applicants' attention to Section 803.02 of the MPEP, the subsection that addresses Markush-type claims:

"This subsection deals with Markush-type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush-type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the

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merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.”

Therefore, the claims herein lack unity of invention under MPEP 803.02, since the compounds defined in the claims lack a significant structural element qualifying as the substantial structural feature that defines a contribution over the prior art. The compounds claimed contain only a pyrrole ring in common, which does not define a contribution over the prior art. Attached to the instant office action is a copy of a reference that provides that the technical feature, which can be taken as a whole amongst all the alternatives, as depicted above, is not a ‘substantial structural feature’ as defined in MPEP 803.02, by failing to define a contribution over the prior art, as it was known in the art prior to the filing of the instant application. Please see attached Huebner et al reference, which discloses a substituted pyrrole compound.

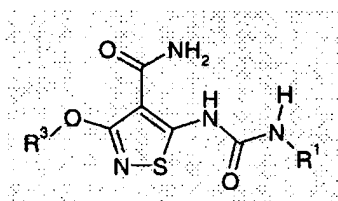
Furthermore, the substituents vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

5. The requirement is still deemed proper and is therefore made FINAL. Claims 14 and 15 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected inventions, there being no allowable generic or linking claim.

Status of the Claims

6. Claims 1-15 pending in this application. Claims 14 and 15, drawn to methods of use, are currently withdrawn from consideration by the Examiner. The scope of the invention of the elected subject matter is as follows:

Compounds according to formula (I), with the core structure:



wherein: R³ is pyridinyl and the remaining variables are as defined.

As a result of the election and the corresponding scope of the invention identified above, the remaining subject matter of claims 1-13 **withdrawn** from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions (i.e. compounds and compositions within claims 1-13 that are excluded from the scope of the invention defined above, when R³ is not pyridinyl). The withdrawn compounds contain varying functional groups for the R³ moiety including pyrazinyl, pyrimidinyl, pyridazinyl, thienyl, furyl, imidazolyl, pyrrolyl, oxazolyl, thiazolyl, pyrazolyl, tetrazolyl, triazolyl, oxadiazolyl, thiadiazolyl, quinolyl, benzothienyl, benzofuryl, indolyl, azetidiny, tetrahydrofuranyl, piperidinyl, thiomorpholinyl, tetrahydrothiazinyl, oxetanyl, oxazinyl, quinuclidinyl, chromanyl, benzocazinyl, and the like (please refer to pages 7 and 8 of the specification), which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e. class 544 (pyrimidinyl), class 546 (pyradinyl), class 548 (oxazolyl), and class 549 (thienyl). Therefore the subject matter that has been withdrawn from consideration as being non-elected subject

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matter, differs materially in structure and composition and has been restricted properly, and a reference that anticipates the elected subject matter would not render obvious the withdrawn subject matter, and the fields of search would not be coextensive.

7. It is suggested that in order to advance prosecution, the non-elected subject matter of claims 1-13 as well as method claims 14-15 in their entirety be canceled when responding to this Office Action. Applicant is reminded that upon the cancellation of subject matter to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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10. The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

11. Claims 1-13 rejected under 35 U.S.C. 103(a) as being obvious over Larson et al, U.S. 6,235,764.

Applicants are claiming the following compounds:

Applicants are claiming isothiazole derivatives according to formula (I) and the above-identified examined invention (as described in paragraph 6) that are useful for treating hyperproliferative diseases such as cancer.

Determining the scope and content of the prior art

Larson et al teach isothiazole derivatives having the same core structure and falling into the same definition of the invention, please see formula I in column I, for example. The

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compounds disclosed in the Larson et al patent fully encompass the compounds of the instant invention and are also useful for treating hyperproliferative diseases, especially cancer.

Ascertaining the difference between the prior art and the claims

The difference between the prior art and the claims is that Larson et al do not teach a single disclosed compound or species that anticipates the instant claims.

Resolving the level of ordinary skill in the pertinent art

However, minus a showing of unobvious results, it would have been obvious to one of skill in the art to prepare the isothiazole compounds as instantly claimed in claims 1- 13 since the prior art reference discloses a similar genus of isothiazoles with anti-hyperproliferative activity. Larson et al teach a larger genus of compounds that completely encompass the smaller genus that is instantly claimed as formula (I). One would be motivated to prepare the instantly claimed invention since Larson et al have enabled and taught the broad scope of compounds in the many examples and variations disclosed in the '764 patent, for example in columns 4-6. The Examiner directs Applicant's attention to column 1, Formula 1, wherein R³ can be pyridyl and one of R1 and R2 is hydrogen and the other is heterocyclic-alkyl [i.e. "-(CH₂)_i(4-10 membered heterocyclic)"]. One skilled in the art would know to pick and choose from the various substituents disclosed and the same ureido-isothiazole-carboxylic acid amide backbone as guided by Larson et al, particularly when they possess the same activity and share the same utility of treating hyperproliferative disorders. Therefore, absent a showing of unobvious and superior properties, the instant claimed genus of isothiazole derivatives would have been suggested to one skilled in the art.

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Conclusion

12. In conclusion, claims 1-15 are pending, however claims 14 and 15 are withdrawn from consideration as directed to non-elected subject matter. Claims 1-13 are currently rejected.

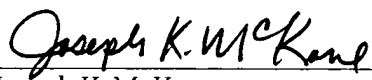
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
February 18, 2005



Joseph K. McKane,
SPE, Art Unit 1626